K121445

BECKMAN COULTER

JUL 2 6 2013

Special 510(k) Summary for CYTO-STAT® tetraCHROME™ CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5, CYTO-STAT® tetraCHROME™ CD45-FITC/CD56-RD1/CD19-ECD/CD3-PC5, and tetraCXP SYSTEM for Cytomics FC 500 with CXP Software

1.0 Submitted By:

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2.0 Date Submitted:

May 14th, 2012

3.0 Device Name and Classification

Proprietary Name:
CYTO-STAT® tetraCHROME™ CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5
CYTO-STAT® tetraCHROME™ CD45-FITC/CD56-RD1/CD19-ECD/CD3-PC5

Classification Number: 21 CFR § 864.5220 – Automated differential cell counter

Classification: Class II

Product Code: GKZ

Panel: Hematology

Proprietary Name:
tetraCXP SYSTEM for Cytomics FC 500 with CXP Software

Classification Number: 21 CFR § 864.5220 – Automated differential cell counter

Classification: Class II

Product Code: GKZ

Panel: Hematology

4.0 Predicate Devices:

Predicate Device	510(K) Number	Date Cleared	Classification	21 CFR	Product Code
tetraCHROME Reagents	K030408	3/4/2003	Class II	864.5220	GKZ
tetraCXP SYSTEM for Cytomics FC 500 Flow Cytometer with CXP Software	K030828	5/21/2003	Class II	864.5220	GKZ

The change in this Special 510(k) is to labeling claims for specimen and prepared sample stability. There are no formulation or process changes to the reagents and no hardware or software changes to the instrumentation as a result of this these changes.

5.0 Description:

CYTO-STAT tetraCHROME CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5 Monoclonal Antibody Reagent

This monoclonal antibody reagent identifies a lymphocyte gate based on CD45 bright positive staining (vs. side scatter) and allows simultaneous identification and enumeration of total CD3+, total CD4+ total CD8+, dual-positive CD3+/CD4+ and dual-positive CD3+/CD8+ lymphocytes in whole blood by flow cytometry.

The reagent is comprised of four murine monoclonal antibodies. Each antibody is labeled with a different color fluorochrome.

The reagent is for use on the COULTER EPICS XL/XL-MCL and Cytomics FC 500 Flow Cytometers with a manual gating procedure provided in the reagent product labeling. The reagent may also be used with the automated algorithm gating provided by tetraONE SYSTEM for COULTER EPICS XL/XL-MCL Flow Cytometers or tetraCXP SYSTEM for Cytomics FC 500 Flow Cytometers.

CYTO-STAT tetraCHROME CD45-FITC/CD56-RD1/CD19-ECD/CD3-PC5 Monoclonal Antibody Reagent

This monoclonal antibody reagent identifies a lymphocyte gate based on CD45 bright positive staining (vs. side scatter) and allows simultaneous identification and enumeration of total CD3+, CD19+ and CD3-/CD56+ lymphocytes in whole blood by flow cytometry.

The reagent is comprised of four murine monoclonal antibodies. Each antibody is labeled with a different color fluorochrome.

The reagent is for use on the COULTER EPICS XL/XL-MCL and Cytomics FC 500 Flow Cytometers with a manual gating procedure provided in the reagent product labeling. The reagent may also be used with the automated algorithm gating provided by tetraONE SYSTEM

for COULTER EPICS XL/XL-MCL Flow Cytometers or tetraCXP SYSTEM for Cytomics FC 500 Flow Cytometers.

tetraCXP SYSTEM

tetraCXP SYSTEM for the Cytomics FC 500 with CXP Software consists of tetraCXP SYSTEM application software, tetraCHROME monoclonal antibody reagents, quality control reagents, an optional absolute count reagent, and automated software on the Cytomics FC 500 Flow Cytometer.

The system with CYTO-STAT tetraCHROME CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5 allows for simultaneous identification and enumeration of total CD3+,,total CD4+, total CD8+, dual CD3+/CD4+ and dual CD3+/CD8+ T lymphocyte population percentages and absolute counts. The system also provides the CD4/CD8 ratio.

The system with CYTO-STAT tetraCHROME CD45-FITC/CD56-RD1/CD19-ECD/CD3-PC5 is intended "For In Vitro Diagnostic Use" and allows simultaneous identification and enumeration of total CD3+ (T), CD19+ (B), and CD3-/CD56+ (NK) lymphocyte population percentages and absolute counts.

The tetraCXP SYSTEM Software comprises two functions: an Auto-Set Panel and an Automated Analysis Algorithm. The Auto-Set Panel automatically standardizes the cytometer, adjusts compensation settings, passes cytometer settings to designated test protocols, and verifies cytometer setup and antibody performance. Compensation settings are determined using QuickCOMP 4 Cells. The Automated Analysis Algorithm works in conjunction with the tetraCHROME monoclonal antibodies to automatically identify and enumerate sample populations

Principle of Method

The Principal of Method for this test depends upon the ability of a monoclonal antibody to bind to the surface of cells expressing discrete antigenic determinants. Specific cell staining is accomplished by incubating whole blood with monoclonal antibody reagents. The CYTO-STAT tetraCHROME CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5 and CYTO-STAT tetraCHROME CD45-FITC/CD56-RD1/CD19-ECD/CD3-PC5 Monoclonal Antibody Reagents are each a combination of four murine monoclonal antibodies, each conjugated to a specific fluorochrome and specific for different cell surface antigens. Red blood cells are then lysed and the remaining white cells are analyzed on the flow cytometer with either manual gating or automated algorithm gating.

6.0 Intended Use:

tetraCHROME Reagents:

CYTO-STAT tetraCHROME CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5 and CYTO-STAT tetraCHROME CD45-FITC/CD56-RD1/CD19-ECD/CD3-PC5 Monoclonal Antibody Reagents are for use on the COULTER EPICS XL/XL-MCL and Cytomics FC 500 Flow Cytometers. The reagents may also be used with the tetraONE SYSTEM for COULTER EPICS XL/XL-MCL Flow Cytometers or with tetraCXP SYSTEM for Cytomics FC 500 Flow Cytometers.

Used alone or in combination with the automated systems, the reagents are intended "For In Vitro Diagnostic Use" and allow simultaneous identification and enumeration of total CD3+, total CD4+, total CD8+, dual CD3+/CD4+, dual CD3+/CD8+ and/or total CD3+, CD19+ and CD3-/CD56+ lymphocyte percentages and absolute counts in whole blood by flow cytometry. The systems also provide the CD4/CD8 ratio when using CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5.

tetraCXP SYSTEM:
The tetraCXP Software for Cytomics FC 500 flow cytometry systems, CYTO-STAT tetraCHROME CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5, and CYTO-STAT tetraCHROME CD45-FITC/CD56-RD1/CD19-ECD/CD3-PC5 Monoclonal Antibody Reagents combine four-color fluorescent monoclonal antibody reagents, quality control reagents, an optional absolute count reagent, and software for automated analysis of lymphocyte populations in whole blood using Cytomics FC 500 flow cytometry systems with CXP Software.

The system with CYTO-STAT tetraCHROME CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5 is intended "For In Vitro Diagnostic Use" and allows simultaneous identification and enumeration of total CD3+, total CD4+, total CD8+, dual CD3+/CD4+ and dual CD3+/CD8+ T lymphocyte population percentages and absolute counts. The system also provides the CD4/CD8 ratio.

The system with CYTO-STAT tetraCHROME CD45-FITC/CD56-RD1/CD19-ECD/CD3-PC5 is intended "For In Vitro Diagnostic Use" and allows simultaneous identification and enumeration of total CD3+ (T), CD19+ (B), and CD3-/CD56+ (NK) lymphocyte population percentages and absolute counts. This reagent reflects the distribution of the three major subsets comprising the lymphocyte population upon which other lymphocyte enumeration studies are based.

7.0 Comparison to Predicates:

The modified tetraCHROME reagents and tetraCXP SYSTEM have the following similarities to those which previously received 510(k) clearance:

- have the same fundamental indicated use,
- use the same operating principle,
- incorporate the same design (no changes to hardware, software or reagents),
- incorporate the same materials,
- have the same shelf life, and
- are packaged using the same materials and processes.

The changes to these devices are limited to the claims made in the product labeling for specimen and prepared sample stability claims.

8.0 Summary of Performance Data:

Study	Study Design	Study Results
Specimen and prepared sample stability studies	Specimens tested at various time intervals to demonstrate sample and prepared sample stability. Upper limit of the drift is compared against the acceptance limits.	Acceptable sample and prepared sample stability results achieved.

9.0 Conclusion:

The data in the Premarket Notification on safety and effectiveness supports a finding that the modified tetraCXP SYSTEM, CYTO-STAT tetraCHROME CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5 and CYTO-STAT tetraCHROME CD45-FITC/CD56-RD1/CD19-ECD/CD3-PC5 Monoclonal Antibody Reagents are substantially equivalent to their respective predicate devices.

This summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807.92.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

July 26, 2013

Beckman Coulter, Inc.
C/O Nancy Nadler, Group Manager, Regulatory Affairs
11800 S.W. 147 Ave.
MIS 31-B06
Miami, Florida 33196-2500

Re: 510(k) Number:	k121445
Trade/Device Name:	CYTO-STAT® tetraCHROME™ CD45-FITC/CD4-RD 1/CD8-ECD/CD3-PC5 Reagent CYTO-STAT® tetraCHROME™ CD45-FITC/CD56-RD1/CD19-ECD/CD3-PC5 Reagent tetraCXP SYSTEM for Cytomics FC 500 with CXP Software
Regulation Number:	21 CFR 864.5220
Regulation Name:	Automated differential cell counter.
Regulatory Class:	Class II
Product Code:	OYE
Dated:	July 5, 2013
Received:	July 10, 2013

Dear Ms. Nadler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M. Chan -S

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K121445

Device Name: CYTO-STAT® tetraCHROME™ CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5
CYTO-STAT® tetraCHROME™ CD45-FITC/CD56-RD1/CD19-ECD/CD3-PC5
tetraCXP SYSTEM for the Cytomics FC 500 with CXP Software

Indication for Use:

tetraCHROME Reagents:

CYTO-STAT tetraCHROME CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5 and CYTO-STAT tetraCHROME CD45-FITC/CD56-RD1/CD19-ECD/CD3-PC5 Monoclonal Antibody Reagents are for use on the COULTER EPICS XL/XL-MCL and Cytomics FC 500 Flow Cytometers. The reagents may also be used with the tetraONE SYSTEM for COULTER EPICS XL/XL-MCL Flow Cytometers or with tetraCXP SYSTEM for Cytomics FC 500 Flow Cytometers.

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The system with CYTO-STAT tetraCHROME CD45-FITC/CD56-RD1/CD19-ECD/CD3-PC5 is intended "For In Vitro Diagnostic Use" and allows simultaneous identification and enumeration of total CD3+ (T), CD19+ (B), and CD3-/CD56+ (NK) lymphocyte population percentages and absolute counts. This reagent reflects the distribution of the three major subsets comprising the lymphocyte population upon which other lymphocyte enumeration studies are based.

Prescription Use ___X___ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health

Reena Philip -S

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k121445